

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

**CERTIFICATION OF SETH  
A. GOLDBERG, ESQ.**

SETH A. GOLDBERG, ESQ., being of full age, certifies as follows:

1. I am a Partner at Duane Morris LLP, attorneys for Defendants Zhejiang Huahai Pharmaceutical Co, Ltd., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC. I am also Lead Counsel and Liaison Counsel for all Defendants in this MDL. I make this Certification based on personal knowledge and in support of the Defendants' Joint Motion to Exclude the Opinions of Stephen Hecht, Ph.D.
2. Attached hereto as Exhibit A is a true and accurate copy of the expert report of Stephen Hecht, PhD, dated July 6, 2021, served in MDL 2875.
3. Attached hereto as Exhibit B is a true and accurate copy of FDA News Release titled "FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity," dated July 13, 2018.
4. Attached hereto as Exhibit C is a true and correct copy of FDA News Release titled, "FDA provides update on its ongoing investigation into valsartan

products; and reports on the finding of an additional impurity identified in one firm's already recalled products," dated Sep. 13, 2018.

5. Attached hereto as Exhibit D is a true and correct copy of IARC - Summaries and Evaluations on N-Nitrosodimethylamine.

6. Attached hereto as Exhibit E is a true and correct copy of IARC - Summaries and Evaluations on N-Nitrosodiethylamin.

7. Attached hereto as Exhibit F is a true and correct copy of IARC Evaluation.

8. Attached hereto as Exhibit G is a true and correct copy of FDA Release, titled FDA, "Information about Nitrosamine Impurities in Medications."

9. Attached hereto as Exhibit H is a true and correct copy of Document titled, "FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)."

10. Attached hereto as Exhibit I is a true and correct copy of document titled, "Laboratory analysis of valsartan products."

11. Attached hereto as Exhibit J is a true and correct copy of the hearing transcript from the July 29, 2020 Case Management Conference.

12. Attached hereto as Exhibit K is a true and correct copy of the hearing transcript from the March 27, 2019 Initial Court Conference.

13. Attached hereto as Exhibit L is a true and correct copy of Environmental Protection Agency Fact Sheet, “Technical Fact Sheet – N-Nitrosodimethylamine (NDMA),” dated January 2014.

14. Attached hereto as Exhibit M is a true and correct copy of National Toxicology Program, *Report on Carcinogens* (14th Ed., 2016).

15. Attached hereto as Exhibit N is a true and correct copy of the transcripts of Days 1 and 2 of the deposition of Stephen Hecht, PhD, in MDL 2875, dated August 17, 2021, and August 18, 2021.

16. Attached hereto as Exhibit O is a true and correct copy of “Comparative Tumorigenicity and DNA Methylation in F344 Rats by 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone and N-nitrosodimethylamine” by Stephen Hecht, et al.

17. Attached hereto as Exhibit P is a true and correct copy of “The Production of Malignant Primary Hepatic Tumours in the Rat by Feeding Dimethylnitrosamine” by P.N. Magee and J.M. Barnes.

18. Attached hereto as Exhibit Q is a true and correct copy of “Pharmacokinetics of N-nitrosodimethylamine in Swine” by C.T. Gombar, et al.

19. Attached hereto as Exhibit R is a true and correct copy of “Use of N-nitrosodimethylamine (NDMA) contaminated valsartan products and risk of cancer: Danish nationwide cohort study” by A. Pottegard, et al.

20. Attached hereto as Exhibit S is a true and correct copy of “N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer” by W. Gomm, et al.

21. Attached hereto as Exhibit T is a true and correct copy of “Critical review of major sources of human exposure to *N*-nitrosamines” by A. Gushgari, et al.

22. Attached hereto as Exhibit U is a true and correct copy of “Effects on 4080 Rats of Chronic Ingestion of N-Nitrosodiethylamine or N-Nitrosodimethylamine: A Detailed Dose-Response Study,” by R. Peto, et al.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg, *Lead Counsel and  
Liaison Counsel for Defendants*

DUANE MORRIS LLP

30 South 17th Street

Philadelphia, PA 19103-4196

Tel.: (215) 979-1000

Fax: (215) 979-1020

SAGoldberg@duanemorris.com

*Attorney for Zhejiang Huahai  
Pharmaceutical Co, Ltd., Prinston  
Pharmaceutical Inc., and Solco  
Healthcare US, LLC*

Dated: November 1, 2021